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NEWSLETTER

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## SCT President's Column



**Lehana Thabane**  
Society for Clinical Trials President 2022-2023

### Program Highlights for the 44th Annual Meeting of the Society for Clinical Trials

We are now in the home stretch in our preparations for the annual meeting of the SCT in Baltimore on May 21-24, 2023. Remember the theme for this year: *Championing High-quality Evidence to Optimize Human Health*. In this column, I want to give you some program highlights from the Education Committee chaired by chaired by Larisa Tereshchenko and co-chaired by Gustavo Jimenez-Maggiara. The Committee has organized an exciting program of pre-conference and in-conference workshops for members to choose from (please see below).

#### Pre-Conference Workshop Titles:

1. Restricted mean survival times for the design and analysis of clinical trials and their meta-analyses
2. Essentials of Clinical Trials
3. Design and Analysis of Randomized Clinical Trials with Real-World Data
4. Leveraging external data through Bayesian methods in clinical trials
5. Statistical and practical aspects of the design and analysis of Multi-Arm Multi-

- Stage (MAMS) Platform Trials
6. Safety and Benefit-Risk Evaluation with Practical Visual Analytical Tools

#### In-Conference Workshop Titles:

1. The statistical analysis of composite time-to-event outcomes
2. Reproducibility and automated reporting in clinical trials
3. Implementation of advanced subject randomization algorithms in complex clinical trials
4. Clinical Trials for Surgical Intervention and Devices: what is IDEAL?

I also remind you that we have also secured two outstanding keynote speakers: **Dr. John Ioannidis (The Curtis Meinert Keynote Speaker)** and **Dr. Kirsten Bibbins-Domingo (The Founders Lecture Keynote Speaker)**. Dr. Ioannidis holds the C.F. Rehnberg Chair in Disease Prevention at Stanford University, where he is Professor of Medicine, Professor of Health Research and Policy, and Professor (by courtesy) of Biomedical Data Science and of Statistics; and Dr. Kirsten Bibbins-Domingo is the Lee Goldman, MD Endowed Professor of Medicine and Professor of Epidemiology and Biostatistics at the University of California, San Francisco. She is currently the 17th Editor in Chief of the Journal of the American Medical Association (JAMA) and the JAMA Network.

The Curtis Meinert Keynote by Dr. Ioannidis is scheduled for Monday, May 22<sup>nd</sup> 8:30 – 9:30 am ET, while the Founders Lecture by Dr. Bibbins-Domingo is on Tuesday, May 23<sup>rd</sup> 8:00 – 9:00 am ET. Don't forget the David Sackett Trial of the Year presentation that is scheduled for Wednes-

## SCT President's Column

day, May 24<sup>th</sup> 8:00 – 9:00 am ET. The David Sackett Trial of the Year Committee is about to finalize their selection of the winner for this year. two keynote speakers.

In my next column, I will bring you some highlights of the main program with invited and contributed sessions along with an update on a special invited panel session on “**Enhancing the Efficiency of Conducting Clinical Trials: Lessons from the COVID-19 Pandemic**”. The panel members will include leaders in clinical trials from regulatory, pharmaceutical, and academic sectors. I will also bring you more details on the titles of our

In the meantime, I strongly encourage to register for the meeting as registration is now open. Please encourage others in your networks to do the same.

Thank you,

*Lehana Thabane,*

SCT President

**Save the Date!**

**44th Annual Meeting of the Society for Clinical Trials!**

**The meeting theme is: “Championing High-quality Evidence to Optimize Human Health.”**

**May 21-24, 2023**

**Baltimore Marriott Waterfront**

**Baltimore, MD**



### **Curtis Meinart Keynote Speaker**

Dr. John Ioannidis

Professor of Medicine (Stanford Prevention Medicine), of Epidemiology and Population Health and By Courtesy, of Statistics and of Biomedical Data Science at Stanford University



### **Founders Lecture Keynote Speaker**

Dr. Kirsten Bibbins-Domingo

Editor-In-Chief, JAMA (Journal of the American Medical Association) and the JAMA Network, and Professor, Epidemiology & Biostatistics and Medicine at the University of California, San Francisco

## February, 2023 Issue Highlights



By Colin Begg, Editor

The **February** issue of *Clinical Trials* is led by a commentary from **Rob Califf**, the FDA head, who provides his views on the evidence generating inadequacies of the clinical trials system, pointing particularly to weaknesses in the post-market phase, and suggesting some areas for focus.

**Martin Karpefors** and colleagues provide a new tool for visualizing composite endpoints in clinical trials.

**Yujie Zhao** and colleagues provide new R software to help in the submission of the electronic common technical document to the FDA.

A team led by **Jonathan Phillips** describe the challenges of recruiting prisoners with mental health issues to clinical trials.

**Christina Bucci-Rechtweg** study FDA and EMA documents in the context of age-inclusive eligibility to address why access of kids to new drugs is significantly delayed. As always we welcome article submissions on any topic related to the conduct of clinical trials.

Follow us on twitter

[@clintrialsj](https://twitter.com/clintrialsj) to keep up to date with the latest from the journal.



## Interested in Presenting an SCT Webinar?

We encourage all SCT members interested in sharing their knowledge and expertise on a particular topic to submit a Webinar Proposal Form for the SCT Education Committee's review and consideration. To access the SCT Sponsored Webinar Proposal Form, go to <https://www.sctweb.org>, click on the Member Sign-In button and login. On the Members-Only Area Home page, click on "Propose a SCT Webinar!" in the menu on the righthand side of the screen. Complete and return the Webinar Proposal Form to [info@sctweb.org](mailto:info@sctweb.org). We look forward to receiving your proposal!

## Highlights From the Web

### NCI Funds More Research Grants Thanks to Action by Congress

On December 29, 2022, President Biden signed legislation that provided funding for NCI, NIH, and other federal government agencies through September 30, 2023.

In this legislation, Congress once again demonstrated its deep concern for people with cancer and strong commitment to the research NCI funds. The legislation signed by the President provides an NCI budget increase of \$386 million for fiscal year (FY) 2023, plus an additional \$22 million for the Cancer Moonshot established by the 21<sup>st</sup> Century Cures Act of 2016. Taken together, this is nearly a 6% increase—the second largest percentage increase for NCI in the past 10 years.

For more information visit the [NCI website](#).



NCI Director Dr. Monica Bertagnolli

# Member Spotlight



Andrew D. Althouse, PhD

## What is your current position?

I am currently a Senior Principal Statistician at Medtronic, working in their Structural Heart & Aortic Unit. Since joining Medtronic, I have worked primarily on clinical trials in transcatheter aortic valve replacement.

## What are your past positions?

Prior to joining Medtronic, I worked as a collaborative statistician in clinical outcomes research for several different groups affiliated with the University of Pittsburgh. Most recently, I worked in the Center for Clinical Trials & Data Coordination (CCDC) under Dr. Kaleab Abebe from 2018 until I was recruited to join Medtronic in October 2022. During that time, I was also the Statistical Editor for *Circulation: Cardiovascular Interventions*, an interventional cardiology journal. I also have previously worked as a core statistician for the UPMC Heart and Vascular Institute; before that, my very first job out of graduate school was at Magee Women's Research Institute.

## What is your training?

I have an undergraduate degree in Statistics from Carnegie Mellon University, a Master's degree in Applied Statistics from the University of Pittsburgh, and a doctoral degree in Epidemiology from the University of Pittsburgh.

## What are your specific research interests?

As a statistician, naturally, I gravitate towards the statistical aspects of clinical trials – novel statistical approaches that help us do clinical trials more efficiently so we can get answers faster and with fewer patients needed while maintaining the same level of rigor and confidence in the results. But whether the statistical methods are particularly novel or not, I find satisfaction in working on any trial that gives us actionable information to improve patient care.

## What are your hobbies (outside of work)?

Lifting weights, raising my 2 sons (currently 4 and 2 years old, respectively)

## What is your favorite part about being involved in clinical trials?

Sharing the results! When the data are all collected, it's time to analyze the data and get the results out there so the medical community has better informed practice.

## Your least favorite?

Paperwork! There is so much paperwork.

## What role(s) did/do you play in SCT?

Social Media Coordinator and Co-Chair of the Communications Committee

## What do you enjoy most about attending the SCT Annual Meeting?

Talking to my peers! It's so great to talk to people that work in different environments and think about how we approach similar problems.

## What advice would you have for junior researchers just starting out in the field of clinical trials?

Working in clinical trials can be very overwhelming if you expect to "know it all" at first; there's really no substitute for on-the-job training. As a statistician – even if you know everything about statistical design and analysis – there are still many other aspects you'll learn and eventually be involved in that you likely never encountered before. What exactly is "monitoring" and who does it during a clinical trial? Will this trial need to provide 100% source document verification, and if so, how will we provide infrastructure to support that need? Don't be too hard on yourself if you find yourself surprised at "how little" it may feel like you know at first. Just keep soaking up information and eventually you become the expert.

## What is one strategy you have used to maintain your sanity during the recent months/years?

Um...see hobbies (lifting weights, raising family). I doubt many would describe the process of raising two very energetic little boys as a relaxing time, but one ancillary benefit is that you almost don't have time to worry about other things too much – you just have to remain in the present and enjoy what's in front of you.

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The Data Coordinating Center (DCC) is a component of the Clinical Trials Program in the Department of Biostatistics and Medical Informatics at the UW School of Medicine and Public Health. The DCC supports investigator-initiated NIH or Industry-sponsored RCTs. We provide expertise in planning, conduct, monitoring, and analysis of clinical trials.

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Berry Consultants is a statistical consulting company specializing in innovative clinical trial design, Bayesian analysis, adaptive clinical trial execution, and simulation software solutions for the pharmaceutical and medical device industry.

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Vertex is a global biotechnology company that invests in scientific innovation to create transformative medicines for people with serious diseases. The company has multiple approved medicines that treat the underlying cause of cystic fibrosis (CF) - a rare, life-threatening genetic disease - and has several ongoing clinical and research programs in CF.

# Save the Dates - Upcoming SCT Annual Meetings



**44th Annual Meeting**  
**May 21-24, 2023**  
**Baltimore, MD**



**45th Annual Meeting**  
**May 19-22, 2024**  
**Boston, MA**



**46th Annual Meeting**  
**May 18-21, 2025**  
**Vancouver, BC, Canada**

## Information About SCT

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